

SUBSTITUTE SPECIFICATION  
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PATENT

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ABSTRACT

This invention relates to the production of polyclonal and monoclonal antibodies to specific regions of cyclosporine (CSA) and/or CSA metabolites/derivatives. The reactivity of these polyclonal and monoclonal antibodies make them particularly useful for immunoassays for therapeutic drug monitoring (TDM). These immunoassays or TDM kits may include polyclonal or monoclonal antibodies to specific sites of CSA and/or CSA metabolites. These kits may also include various combinations of polyclonal antibodies, polyclonal and monoclonal antibodies or a panel of monoclonal antibodies. Cyclosporine or CSA metabolite conjugate immunogens are prepared for the immunization of a host animal to produce antibodies directed against specific regions of the CSA or CSA metabolite molecule. By determining the specific binding region of a particular antibody, immunoassays which are capable of distinguishing between the parent molecule, active metabolites, inactive metabolites and other structurally similar immunosuppressant compounds are developed. The use of divinyl sulfone (DVS) as the linker arm molecule for forming cyclosporine and cyclosporine metabolite protein conjugate immunogens is described.